Culture of Safety of Anesthesia

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Anesthesia is one of the best medical discoveries. The first general anesthesia was given in Japan on October 13, 1804, but this achievement was not recognized in the world due to the closure of Japan. After the first demonstration of ether anesthesia in Boston, USA in 1846, anesthesia quickly spread to the world. The incidence of death-related anesthesia-related accidents was quite high in the early era of anesthesia. The incidence of death during anesthesia was as high as 1 in 1,000 anesthetics in 1890s. The incidence of anesthesia-related deaths was still high, i.e. about 1 : 1500 in the 1950s. There was no systematic approach to the anesthesia-related accidents. Global movement to improve the safety and quality of anesthesia care has started in the 1980s by collecting and analyzing big data. In addition to many guidelines on anesthesia safety, the development of monitors, anesthesia machines with many safety features, and easily controllable medications make anesthesia safer. Vigilance is the foundation of an anesthetic safety culture. Anesthesiologists will make every effort to make perioperative care including anesthetic treatment safer to aim zero mortality and less morbidity.

Key words: anesthesia-related accidents, human error, monitoring standards, vigilance

Introduction

The first general anesthesia for surgery in Japan was performed by Seishu Hanaoka on October 13, 1804. Hanaoka used *mafutsusan*, an herbal concoction containing *Datura alba*. Hanaoka recorded the anesthesia, surgery, and postsurgical course in detail. Hanaoka himself performed over 200 surgeries under general anesthesia. Hanaoka taught students to give anesthesia and surgery. It is said that more than 3,000 operations were performed by Hanaoka's students. Because Japan was closed the country to foreign countries at that time, his achievement was not known to the world.

First public demonstration of ether anesthesia was performed by Wiliam Thomas Green Morton at the Massachusetts General Hospital in Boston, U.S.A. on October 16 in 1846. Chloroform was used

at St. Bartholomew's Hospital, London by Sir William Laurence and Holmes Coote in 1847. Seikei Sugita introduced ether anesthesia to Japan in 1850, only four years after first demonstration of ether anesthesia in the U.S.A. Anesthesia was spread around the world extremely fast.

Anesthesia claimed to be one of the 10 best medical discoveries. Before the discovery of anesthesia, many surgeries were performed without anesthesia. Many patients suffered pain and agony during surgery and died because of surgical stress and infection. However, anesthesia itself carries own risks resulting in dreadful outcome.

History of anesthesia accidents

The first reported death under ether was reported in 1847, and that under chloroform

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351st Triannual Meeting of the Juntendo Medical Society: Farewell Lectures of Retiring Professors [Held on Sep. 30, 2020]

[Received May 26, 2020] [Accepted Aug. 17, 2020]

J-STAGE Advance published date: Sep. 5, 2020

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doi: 10.14789/jmj.2020.66.JMJ20-R11

Table-1 Death rates in Surgical patients classified as to cause. Based Upon 599,548 cases

Cause of death-primary	Number	Rate
Patient's disease	6,325	1 : 95
Surgical error (in diagnosis, judgment, technic)	1,428	1 : 420
Anesthesia death	224	1 : 2,680
Total	7,977	1 : 75
Anesthesia, Primary and contributory	384	1 : 1,560

Table-2 "Curare" agent and associated deaths*

Agent	Uses	Death	Rate
Tubocurarine chloride	9,065	25	1 : 360
Decamethonium bromide	6,147	11	1 : 560
Succinylcholine chloride	699	3	1 : 230
Gallamine tri-ethiodide	448	1	1 : 450
Dimethyl-tubocurarine iodide	221	0	0
Total	16,500	40	1 : 410

*Here counted are uses and associated death only where the curare-like agent was specified for all cases, both living and dead.

anesthesia was in 1848. Other fatal accidents were reported in many countries in a few years after introduction of those anesthesia agents. The concerns about the safety of anesthesia had been expressed since the introduction of anesthesia. Some claimed anesthesia should not be given because of high mortality related to anesthesia. The incidence of death during ether anesthesia was reported 1 in 4,860 cases in England in 1895. The incidence of death during chloroform anesthesia was 1 in 931 cases in Australia in 1897. Although Fredric Hewitt stressed the need for education for safety of anesthesia in 1896, this was not adopted by the General Medical Council until 1912. The systematic progress in anesthesia safety was rather slow in the early times of anesthesia.

Anesthesiologists have empirically learned from anesthesia accidents over time. The Anesthesia Study Commission investigated anesthesia-related fatalities in Philadelphia during the period 1935–1944 and identified respiratory factors such as airway obstruction, hypoxia, and aspiration as the probable cause of death in approximately 19% of cases¹⁾. Emery A. Rovenstine presented case series of nine cardiac arrests in 1951. Beecher and Todd published the landmark article entitled "A study of the deaths associated with anesthesia and surgery*": based on a study of 599,548 anesthetics in ten institutions 1948–1952 inclusive" in 1954²⁾. They

tracked the outcomes of 599,548 anesthetics, identified 7,977 deaths (more than 1 in 100) and classified the causes as from patient disease, surgical error, or anesthesia (Table-1).

They found incidence of mortality related to anesthesia was still high (Table-1). In their study, 7.5% of the deaths reported were attributed to "gross anesthetic mismanagement". Anesthesia was the primary cause of mortality in 1 in 2,680 cases and was contributory in 1 in 1,560 cases. Particularly, the patients who had received neuromuscular blocking drugs such as curare had a significantly higher perioperative morbidity rate (Table-2). It was probably due to respiratory depression. Accidents related respiration had been the major adverse events leading to death and permanent brain injury over the decades. The Canadian study demonstrated that anesthesia-related mortality rate was decreased to 1 : 250,000 for less for ASA 1 and 2 patients³⁾. Modern estimates of anesthesia-related death from throughout the world is as low as 1 in 10,000 anesthetics^{4) 5)}. The processes how the marked decrease in anesthesia-related death will be described.

Role of human error

Previous studies showed that the importance of

human errors in death attributable to anesthesia⁶⁾⁻⁸⁾. Human factor was judged to be the factor attributable to anesthesia death in more than 65% of the cases. Cooper and colleagues published a landmark article demonstrating that human factors played a major role to cause anesthesia incidents and accidents. Overt equipment failure constituted 14% of the total number of preventable incidents. They focused on the process of error including the causes, the circumstances, specific procedures, and equipment. They found 359 preventable incidents by interviewing 47 staff and anesthesia residents and suggested that human error was involved in 82% of the incidents and could have been preventable. They also found that other factors frequently associated with incidents were inadequate communication among personnel, haste or lack of precaution, and distraction. If the circumstances that encourage error were identified and anesthesiologists recognized the risk factors, the frequency of error should be decreased. Since the basic monitors including electrocardiogram, blood pressure monitoring, pulse oximetry, thermistor, capnography, neuromuscular monitors, and central nervous system monitor were developed and used in anesthesia, the incidence of anesthesia-related morbidity and mortality has been decreasing. Anesthesia machines equipped with various monitors and human-machine interface to facilitate decision-making and to avoid anesthesia mishaps were developed.

Systematic approach toward the safety of anesthesia in the world

Worldwide movements toward the safety of anesthesia has started in 1980s. Cooper, Kitz, and Pierce at Harvard Medical School hosted a landmark International Symposium on Preventable Anesthesia Mortality and Morbidity in Boston in 1984. Approximately 50 anesthesiologists from around the world attended the meeting. In 1985, the Anesthesia Patient Safety Foundation (APSF) was established to facilitate anesthesia safety by collecting and analyzing the data associated with anesthesia incidents and accidents, conducting patient safety programs and campaigns, and making the platform for national and international exchange of information and ideas (Table-3).

Anesthesia was the first medical specialty that embraces universally applicable standards.

First, the Department of Anaesthesia of Harvard Medical School, Boston, has devised specific, detailed, mandatory standards for minimal patient monitoring during anesthesia in 1986⁹⁾. I remember the department morning conference regarding this minimal monitoring standards when I was an anesthesia fellow at the Massachusetts General Hospital (MGH), one of the Harvard Medical School affiliated hospitals. There were four objects in this minimal monitoring standards; 1) to improve patient care, thereby reducing the number of adverse outcomes arising from anesthesia accidents, 2) to enhance detection of relatively low-frequency events, 3) to provide a means for objective evaluation, and 4) to establish a precedent. Soon after this monitoring standards were published, Recovery-Room-Impact Events (PRIE) system was started at the MGH¹⁰⁾. PRIE events were defined as an "unanticipated, undesirable, possibly anesthesia-related effect that required intervention. This was the incident reporting system. They found that among 12,088 patients, 18% had at least one PRIE in the operating room or in the recovery room. The common PRIE events were hypotension, arrhythmia, hypertension, intubation difficulties, hypoventilation, and hypovolemia. Intense feedback was provided to facilitate anesthesia safety in the department. I was proud of participating in this project. This Harvard minimal monitoring standards has become the base of the monitoring standards made by the American Society of Anesthesiologists (ASA) and the Japanese Society of Anesthesiologists (JSA).

The Australian Incident Monitoring Study provided a detailed analysis of the first 2,000 cases voluntarily submitted since the late 1980s. In their collection of critical incidents, problems with ventilation accounted for 16% of reports from anesthesiologists in Australia and New Zealand¹¹⁾. Since 1985, the Committee on Professional Liability of the ASA has started the ASA Closed Claims Project. In this project, closed anesthesia claims were collected and structurally analyzed in detail. Standard of care was set to be rated on the basis of reasonable and prudent practices at the time of the event. It became clear that adverse respiratory events were the single largest injury after analyzing more than

Table-3 Selected Areas of Focus of the Anesthesia Patient Safety Foundation, 1985 to 2012

Use of anesthesia simulators for training and evaluation
Improvement of standards for intraoperative monitoring
Application of patient safety checklists to intraoperative care
Promotion of standardized approaches to difficult airway management
Prevention of medication-related adverse events
Reuse and attempted resterilization of disposable anesthesia equipment
Risks of outdated anesthesia machines without modern safety features
Aiding the development of practice standards by the World Federated Societies of Anesthesiologists
Surgery department crisis management, including teamwork, team training, and resource management
Production pressure, causing dangerous omissions and cutting corners
Use of anesthesia simulators for training and evaluation
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Aiding the development of practice standards by the World Federated Societies of Anesthesiologists
Surgery department crisis management, including teamwork, team training, and resource management
Production pressure, causing dangerous omissions and cutting corners
Postoperative cognitive dysfunction (particularly in older adults)
Possible long-term increase in morbidity and mortality after extensive general anesthesia
Postoperative vision loss, especially in extensive prone spine surgery
Wrong-site surgery
Residual neuromuscular blockade and postoperative complications
Protocols for assessing and managing adverse events
Persistence of deaths from malignant hyperthermia
Dangers and challenges in patients with coronary artery stents
Maintenance of current protocols for the anesthesia machine checkout
Possible impact of anesthesia management on cancer recurrence
Persistence of surgical unit fires

(From Eichhorn JH: The Anesthesia Patient Safety Foundation at 25: a pioneering success in safety, 25th anniversary provokes reflection, anticipation. *Anesth Analg*, 2012; 114(4): 791-800)

1,500 closed claims¹²⁾. The major mechanisms of the respiratory events were inadequate ventilation, esophageal intubation, and difficult intubation.

Even after the adoption of the ASA Standards for Basic Anesthesia Monitoring, inadequate ventilation and difficult intubation remained the major mechanisms of the anesthesia-related accidents. Half of all claims for inadequate ventilation were considered preventable with better monitoring, as opposed to 5% of claims for difficult intubation. Then ASA developed an evidence-based guideline for management of the difficult airway in 2003¹³⁾. Because of difficult airway management algorithm and development of better respiratory management devices such as supraglottic airways and video laryngoscopes, the incidence of respiratory events has decreased as well as the number of claims (Figure-1)¹⁴⁾. The JSA reported in 2003 that the average mortality per year within 7 postoperative days to be totally attributable to anesthesia was 0.21 per 10,000 cases¹⁵⁾. The two principal causes of

cardiac arrest during anesthesia and surgery due to all etiologies were massive hemorrhage (31.9%) and surgery surgery-related events (30.2%). Cardiac arrest totally attributable to anesthesia was drug overdose or selection error (15.3%). This report also suggested that preventable human errors caused 53.2% of cardiac arrest and 22.2% of deaths in the operating room totally attributable to anesthesia. The need for establishing the system to eliminate human errors cannot be overemphasized.

Conclusions

The severe anesthesia-related adverse events leading to death or brain injury have dramatically decreased over the past several decades. World-wide movements to collect the data of adverse events and to make guidelines to facilitate safe anesthesia have contributed to this achievement. Anesthesia societies and health care manufacturers work together to make better monitors, anesthesia

Figure-1 (A) The total number of claims by the year of injury. Retrospective data collection began in 1985. Data in this analysis includes data collected through December 2003. (B) Claims for death or permanent brain damage as percentage of total claims per year by year of injury (From Cheney FW, Posner KL, Lee LA, *et al*: Trends in anesthesia-related death and brain damage. *Anesthesiology*, 2006; 105(6): 1081-1086¹⁴⁾)

machines with multiple safety features, and airway management devices in order to contribute the safety of anesthesia and perioperative care. Nowadays, underlying patient disease and the nature and extent of surgery have a greater effect on overall outcome than do risks attributable to the anesthetic.

Vigilance is the base of the culture of anesthesia safety. As Macintosh stated more than 70 years ago, no patient shall be harmed by anesthesia¹⁶⁾. We anesthesiologists should aim not only to avoid anesthesia mishaps but also to improve the short- and long-term outcomes of patients undergoing surgery and anesthesia by establishing the high-standards of care.

Disclosure

The author has no conflict of interest to disclose.

Acknowledgement

The author is deeply grateful to Hideoiki Ogawa, M.D., Ph.D, the CEO of the Juntendo University, for his superb guidance on improving the quality of perioperative and anesthetic care and promoting

the scientific development of anesthesia at the Juntendo-affiliated hospitals.

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